

CLAIMS

1. A composition comprising a monodisperse lipid phase dispersed in a continuous aqueous phase, in which the lipid phase comprises at least one crystallizable lipid, at least one active principle and at least one compound stabilizing the dispersed phase comprising two fatty acid chains and one polyethylene glycol chain.
2. The composition as claimed in claim 1, in which an inner aqueous phase is dispersed in the dispersed lipid phase.
3. The composition as claimed in claim 1 or 2, in which the dispersed lipid phase has a mean diameter of between 0.3 and 10 micrometers.
4. The composition as claimed in one of claims 1 to 3, comprising 0.01% to 30% by weight of lipid phase.
5. The composition as claimed in one of claims 1 to 4, comprising 0.001% to 30% by weight of compound for stabilizing the dispersed phase.
6. The composition as claimed in one of claims 1 to 5, in which the polyethylene glycol chain comprises 25 to 1000 ethylene glycol units.
7. The composition as claimed in one of claims 1 to 6, in which the continuous aqueous phase also comprises 0.001% to 10% by weight of a thickener.
8. The composition as claimed in claim 7, in which the thickener is an alginic acid salt.

9. The composition as claimed in one of claims 1 to 8, in which the crystallizable lipid is chosen from natural or synthetic fatty acid mono-, di- or triglycerides, natural or synthetic waxes, wax alcohols and esters thereof, fatty alcohols and esters and ethers thereof, fatty acids and esters thereof, fatty acid glycerides and hydrogenated plant or animal oils, alone or as a mixture.
10. The composition as claimed in claim 9, in which the crystallizable lipid is a C₁₂-C₁₈ mono-, di- or triglyceride.
11. The composition as claimed in one of claims 1 to 10, in which the continuous aqueous phase comprises a cryoprotective agent.
12. The composition as claimed in claim 11, in which the cryoprotective agent is a polyol or a salt.
13. The composition as claimed in one of claims 1 to 12, in which the lipid phase comprises at least two active principles.
14. The composition as claimed in one of claims 1 to 13, in which the lipid phase comprises at least one water-soluble active principle.
15. The composition as claimed in one of claims 1 to 14, in which the lipid phase comprises at least one sparingly water-soluble active principle.
16. The composition as claimed in one of claims 1 to 15, in which the lipid phase comprises at least one water-soluble active principle and at least one sparingly water-soluble active principle.
17. The composition as claimed in one of claims 1 to 16, in which the active principle is chosen from

the group of pharmaceutical, veterinary, plant-protection, cosmetic and agrifood active principles.

5 18. The composition as claimed in one of claims 1 to 17, in which the active principle is a detergent, a nutrient, an antigen or a vaccine.

10 19. The composition as claimed in one of claims 1 to 18, in which the water-soluble pharmaceutical active principle is chosen from the group consisting of antibiotics, hypolipidemiants, antihypertensives, antiviral agents, beta blockers, bronchodilators, cytostatic agents, 15 psychotropic agents, hormones, vasodilators, anti-allergic agents, antalgic agents, antipyretic agents, antispasmodic agents, anti-inflammatory agents, anti-angiogenic agents, antibacterial agents, antiulcer agents, antifungal agents, anti-parasitic agents, antidiabetic agents, anti- 20 epileptic agents, antiparkinsonian agents, anti-migraine agents, anti-Alzheimer's agents, antiacne agents, antiglaucoma agents, antiasthmatic agents, neuroleptics, antidepressants, anxiolytics, hypnotics, normothymic agents, sedatives, psychostimu- 25 lants, anti-osteoporosis agents, antiarthritic agents, anticoagulants, antipsoriasis agents, hyperglycemiants, orexigenic agents, anorexigenic agents, antiasthenic agents, anticonstipation agents, antidiarrhea agents, antitrauma agents, 30 diuretics, muscle relaxants, enuresis medicaments, erectile dysfunction medicaments, vitamins, peptides, proteins, anticancer agents, nucleic acids, RNA, oligonucleotides, ribozymes and DNA.

35

20. The composition as claimed in one of claims 1 to 19, in which the active principle(s) is(are) combined with an agent that modifies the oral absorption or an enzyme inhibitor.

21. The composition as claimed in claim 20, in which the enzyme inhibitor is a P-glycoprotein inhibitor or a protease inhibitor.

5 22. A process for preparing a composition comprising a monodisperse lipid phase dispersed in a continuous aqueous phase, in which the lipid phase comprises at least one crystallizable lipid, at least one active principle and a stabilizer, comprising the
10 steps consisting in:

- i. introducing the active principle(s) into the crystallizable lipid;
- ii. dispersing the lipid phase obtained in the aqueous phase in the presence of a
15 stabilizer, to form an emulsion;
- iii. subjecting the emulsion obtained to a shear to form a monodisperse emulsion.

20 23. A process for preparing a composition comprising a monodisperse lipid phase dispersed in a continuous aqueous phase, in which the lipid phase comprises at least one crystallizable lipid, at least one active principle, a stabilizer and also a dispersed aqueous phase, comprising the steps
25 consisting in:

- dispersing an aqueous solution comprising the active principle(s) in the lipid melt containing, where appropriate, one or more active principles in the presence of a lipophilic surfactant;
- 30 i. subjecting the emulsion obtained to a shear in order to make it monodisperse;
 - ii. incorporating the monodisperse emulsion into an aqueous phase in the presence of a stabilizer to form a double emulsion;
 - 35 iii. subjecting the double emulsion obtained to a shear to form a monodisperse double emulsion.

24. The process as claimed in either of claims 22 and 23, also comprising a cooling step to solidify the dispersed lipid phase.

5 25. A process for preparing monodisperse lipid particles comprising at least one active principle, comprising the removal of the aqueous phase of a composition prepared according to the process of one of claims 22 to 24.

10

26. The process as claimed in claim 25, in which the aqueous phase is removed by freeze-drying, if necessary after diluting the composition in a solution containing a cryoprotective agent.

15

27. The use of the compositions as claimed in one of claims 1 to 21 or of the monodisperse lipid particles that may be obtained according to the processes as claimed in one of claims 22 to 26, for the preparation of active principle delivery systems.

20